Gastroenterology and Urology Devices Panel Questions

May 14-15, 2015

The panel will be asked to answer the following questions:

1. You have been provided information regarding the methodology and criteria for acceptance of cleaning, high-level disinfection, and sterilization validation testing, for both manual and automated processes. Do duodenoscopes and AERs that meet these requirements provide a reasonable assurance of safety and effectiveness?

    a. If not, what additional methodology and criteria, should be incorporated into the validation of cleaning and high level disinfection and/or sterilization of duodenoscopes? Please discuss the role of the duodenoscope manufacturer, AER manufacturer, high level disinfectant manufacturer, sterilizer manufacturer, and FDA.

    b. If the panel recommends changes, are these changes specific to duodenoscopes and AERs, or should changes be considered for other medical devices covered in FDA's Reprocessing Guidance (published in March 2015)?

2. Considering the risk of error with manual reprocessing, and alternate cleaning and sterilization technologies:

    a. What is the role of pre-market human factors testing in the development of reprocessing instructions? Should this testing be evaluated differently for manual cleaning, AERs, and sterilizers?

b. What recommendations would the panel have for end user training, certification, etc. for ensuring user adherence with manufacturer's reprocessing instructions?

3. Some healthcare facilities reprocess endoscopes with cleaning agents and brushes that differ from the endoscope manufacturer's instructions, and may utilize cleaning verification assays and channel flushing aids for cleaning. Cleaning agents are not medical devices, brushes are class I medical devices and are not reviewed by FDA, and neither cleaning verification assays nor channel flushing aids for cleaning have been reviewed by FDA. What measures, if any, should be taken to ensure that these products used during cleaning demonstrate adequate performance? What responsibilities should FDA, industry, professional organizations, standards organizations, and healthcare facilities have in ensuring the products perform as intended? What changes to these products would be significant enough to warrant reassessment?

4. In March 2015, the CDC issued interim guidance for surveillance for bacterial contamination of duodenoscopes after reprocessing. Does the panel recommend these practices be implemented by healthcare facilities as a best practice, or would these practices be best suited for specific facilities where outbreaks have occurred?

5. What is the panel's recommended approach for ensuring patient safety for ERCP procedures? What information about the risks of infection should be provided to patients prior to ERCP? Please include a discussion on appropriate patient selection,

informed consent, methods of communication, and use of other measures that mitigates risk of infection in patients.

6. FDA is interested in hearing your thoughts on when and how to share information with the public about situations similar to the focus of this Advisory Committee Meeting. When we have a medical device concern, but not enough information to determine the most appropriate action towards resolution, what temporizing measures should FDA consider doing while a more definitive solution is sought? Specifically, what would be the appropriate time / method for us to communicate with stakeholders (hospitals, manufacturers, patients, etc.)?